

5170--A

Cal. No. 825

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I N   S E N A T E

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Introduced by Sens. HANNON, AMEDORE, MURPHY, ORTT, BOYLE, CROCI, GOLDEN, HASSELL-THOMPSON, MARTINS -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- reported favorably from said committee, ordered to first and second report, ordered to a third reading, amended and ordered reprinted, retaining its place in the order of third reading

AN ACT to amend the public health law and the insurance law, in relation to the use of abuse-deterrent technology for opioids as a mechanism for reducing abuse and diversion of opioid drugs

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

1     Section 1. The public health law is amended by adding a new section  
2     3340 to read as follows:  
3     S 3340. SUBSTITUTION OF OPIOIDS WITH ABUSE-DETERRENT TECHNOLOGY. 1.  
4     NOTWITHSTANDING THE PROVISIONS OF SECTION SIXTY-EIGHT HUNDRED SIXTEEN-A  
5     OF THE EDUCATION LAW, NO PHARMACIST SHALL INTERCHANGE OR SUBSTITUTE AN  
6     ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT, BRAND OR GENERIC, WITH AN  
7     OPIOID ANALGESIC DRUG PRODUCT LACKING ABUSE-DETERRENT PROPERTIES WHEN  
8     THE PRESCRIBER WRITES OR ELECTRONICALLY NOTATES "DISPENSE AS WRITTEN" OR  
9     "DAW" ON THE PRESCRIPTION, WITHOUT OBTAINING A NEW PRESCRIPTION FOR A  
10    NON-ABUSE DETERRENT OPIOID DRUG FROM THE PRESCRIBER. ANY SUBSTITUTABLE  
11    OPIOID DRUG PRODUCT SHALL CONTAIN THE SAME OPIOID ACTIVE PHARMACEUTICAL  
12    INGREDIENT AND THE SAME DRUG RELEASE CHARACTERISTICS WITH REGARD TO  
13    IMMEDIATE RELEASE, OR EXTENDED RELEASE LONG ACTING PROPERTIES. A DETER-  
14    MINATION OF INTERCHANGEABILITY BETWEEN TWO ABUSE-DETERRENT OPIOID ANAL-  
15    GESIC DRUG PRODUCTS SHALL NOT REQUIRE THAT BOTH PRODUCTS INCORPORATE THE  
16    SAME METHODS OF ABUSE-DETERRENCE, BUT THAT THE OPIOID DRUG PRODUCTS HAVE  
17    THE SAME LEVEL OF FDA-APPROVED ABUSE DETERRENCE LABELING CLAIMS.  
18    2. DEFINITIONS. AS USED IN THIS SECTION:  
19    (A) "OPIOID ANALGESIC DRUG PRODUCT" MEANS A DRUG IN THE OPIOID ANAL-  
20    GESIC DRUG CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER

EXPLANATION--Matter in *ITALICS* (underscored) is new; matter in brackets [ ] is old law to be omitted.

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1 CONDITIONS, WHETHER IN IMMEDIATE RELEASE OR EXTENDED RELEASE LONG ACTING  
2 FORM AND WHETHER OR NOT COMBINED WITH OTHER DRUG SUBSTANCES TO FORM A  
3 SINGLE DRUG PRODUCT OR OTHER DOSAGE FORM.

4 (B) "ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT" MEANS A BRAND OR  
5 GENERIC OPIOID ANALGESIC DRUG PRODUCT APPROVED BY THE FEDERAL FOOD AND  
6 DRUG ADMINISTRATION WITH ABUSE-DETERRENCE LABELING CLAIMS INDICATING ITS  
7 ABUSE-DETERRENT PROPERTIES ARE EXPECTED TO DETER OR REDUCE ITS ABUSE.

8 (C) "INTERCHANGE OR SUBSTITUTION OF AN OPIOID DRUG" MEANS THE SUBSTI-  
9 TUTION OF ANY ABUSE-DETERRENT OPIOID DRUG PRODUCT, BRAND OR GENERIC,  
10 WITH AN OPIOID ANALGESIC DRUG LACKING ABUSE-DETERRENT PROPERTIES.

11 (D) "PHARMACIST" INCLUDES ANY PHARMACIST DISPENSING DRUGS UNDER THE  
12 JURISDICTION OF THE STATE BOARD OF PHARMACY, INCLUDING BUT NOT LIMITED  
13 TO, COMMUNITY PHARMACISTS, PHARMACISTS IN HOSPITAL-BASED PHARMACIES WHEN  
14 FILLING PRESCRIPTIONS FOR INPATIENT OR OUTPATIENT CARE, AND PHARMACISTS  
15 IN MAIL ORDER PHARMACIES LICENSED BY THE STATE TO DISTRIBUTE IN THE  
16 STATE.

17 S 2. The insurance law is amended by adding a new section 3216-a to  
18 read as follows:

19 S 3216-A. ACCESS TO ABUSE-DETERRENT OPIOID MEDICATIONS. (A) AN INSUR-  
20 ANCE CARRIER OR HEALTH PLAN SHALL PROVIDE COVERAGE ON ITS FORMULARY,  
21 DRUG LIST OR OTHER LISTS OF SIMILAR CONSTRUCT FOR AT LEAST ONE  
22 ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT PER OPIOID ANALGESIC  
23 ACTIVE INGREDIENT.

24 (1) COST-SHARING FOR BRAND NAME ABUSE-DETERRENT OPIOID ANALGESIC DRUG  
25 PRODUCTS COVERED PURSUANT TO THIS SECTION SHALL NOT EXCEED THE LOWEST  
26 COST-SHARING LEVEL APPLIED TO BRAND NAME NON-ABUSE DETERRENT OPIOID  
27 DRUGS COVERED UNDER THE APPLICABLE HEALTH PLAN OR POLICY.

28 (2) COST-SHARING FOR GENERIC ABUSE-DETERRENT OPIOID ANALGESIC DRUG  
29 PRODUCTS COVERED PURSUANT TO THIS SECTION SHALL NOT EXCEED THE LOWEST  
30 COST-SHARING LEVEL APPLIED TO GENERIC NON-ABUSE DETERRENT OPIOID DRUGS  
31 COVERED UNDER THE APPLICABLE HEALTH PLAN OR POLICY.

32 (3) AN INCREASE IN PATIENT COST-SHARING OR DISINCENTIVES FOR PRESCRI-  
33 BERS OR DISPENSERS SHALL NOT BE ALLOWED TO ACHIEVE COMPLIANCE WITH THIS  
34 SECTION.

35 (B) ANY PRIOR-AUTHORIZATION REQUIREMENTS OR OTHER UTILIZATION REVIEW  
36 MEASURES FOR OPIOID ANALGESICS, AND ANY SERVICE DENIALS MADE PURSUANT  
37 THERETO, SHALL NOT REQUIRE USE OF OPIOID ANALGESIC DRUG PRODUCTS WITHOUT  
38 ABUSE-DETERRENT PROPERTIES IN ORDER TO ACCESS ABUSE-DETERRENT OPIOID  
39 ANALGESIC DRUG PRODUCTS.

40 (C) DEFINITIONS. AS USED IN THIS SECTION:

41 (1) "OPIOID ANALGESIC DRUG PRODUCT" MEANS A DRUG IN THE OPIOID ANAL-  
42 GESIC DRUG CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER  
43 CONDITIONS, WHETHER IN IMMEDIATE RELEASE OR EXTENDED LONG ACTING RELEASE  
44 FORM AND WHETHER OR NOT COMBINED WITH OTHER DRUG SUBSTANCES TO FORM A  
45 SINGLE DRUG PRODUCT OR OTHER DOSAGE FORM.

46 (2) "ABUSE DETERRENT OPIOID ANALGESIC DRUG PRODUCT" MEANS A BRAND OR  
47 GENERIC OPIOID ANALGESIC DRUG PRODUCT APPROVED BY THE FEDERAL FOOD AND  
48 DRUG ADMINISTRATION WITH ABUSE-DETERRENCE LABELING CLAIMS INDICATING ITS  
49 ABUSE-DETERRENT PROPERTIES ARE EXPECTED TO DETER OR REDUCE ITS ABUSE.

50 (3) "COST-SHARING" MEANS ANY COVERAGE LIMIT, COPAYMENT, COINSURANCE,  
51 DEDUCTIBLE OR OTHER OUT-OF-POCKET PATIENT EXPENSE REQUIREMENTS.

52 S 3. This act shall take effect on the one hundred twentieth day after  
53 it shall have become a law, and shall apply to all policies and  
54 contracts issued, renewed, modified, altered or amended on or after such  
55 date.